

COMMENT REGARDING PROPOSED RULEMAKING ON PROFICIENCY TESTING FOR GYNECOLOGIC CYTOLOGY

Members of the committee, CMS and CDC personnel, thank you for the opportunity to present this statement. I am George Birdsong, M.D. speaking for the Cytology Education and Technology Consortium (CETC). The CETC is made up of representatives from the American Society of Cytopathology, American Society of Cytotechnology, Papanicolaou Society of Cytopathology, American Society for Clinical Pathology, International Academy of Cytology, and the College of American Pathologists (CAP), all of which are major national and international professional organizations with an interest in the practice of cytopathology. The CETC opposes withdrawal of the proposed rule regarding cytology proficiency testing. Among the reasons for opposition to withdrawal of the proposed rule are:

- Published concerns regarding the psychometric validity of the test¹⁻⁴
- Recently published data indicating that overcalls (false positives) increase in the PT environment⁵
- Lack of demonstrated robust clinical validation of the test

Although there was not 100% consensus on how best to revise cytology proficiency testing, there is a clear majority of practitioners who feel that the benefit of the current program is questionable. The CAP is collaborating with CDC to examine all aspects of quality assurance practices in gynecologic cytopathology, including proficiency testing. A consensus conference will be convened on June 4, 2011. We would like to revisit the question of how best to comply with the statutory CLIA '88 requirement for "Periodic confirmation and evaluation..." of the performance of cytology professionals after results of this conference are available.

Thank you for the opportunity to speak to the committee, CMS, and CDC officials.

REFERENCES

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